Δ LIPUS Health Utility and Economic Analysis

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Background/Purpose: Tibial fractures are common and costly injuries that disproportionally affect young men in the prime of their working lives. Low-intensity, pulsed ultrasound (LIPUS) is a form of bone stimulation that is often used to augment fracture healing. Despite this high rate of use, the evidence to support the widespread adoption of LIPUS is limited and inconclusive, with most trials having focused on surrogate outcomes of recovery (radiographic healing). Our group recently completed a 501-patient, multicenter, randomized controlled trial to establish the effect of LIPUS on tibial shaft fractures managed with intramedullary nailing. We conducted an economic evaluation as part of this trial.

Methods: For each arm of the trial we calculated resource use and estimated costs of hospitalization and other components of treatment. We collected and converted Health Utilities Index version III (HUI-III) scores (a health status classification system that yields a mean score per group on the interval from death [=0] to perfect health [=1]) at baseline and follow-up into Quality-Adjusted Life Years (QALYs). Finally, we evaluated the cost-effectiveness of LIPUS from 2 perspectives: (1) the perspective of the payer, which will include direct health-care costs only, and (2) the societal perspective, which included both direct costs and indirect costs (eg, time lost from work).

Results: We acquired HUI-III data from 481 of 501 (96%) patients, which showed no difference between treatment and control groups (mean difference = 0.032; 95% CI: -0.004, 0.068). The incremental cost effectiveness ration (ICER) was $61,530/QALY from a payer perspective, and $63,646/QALY from a societal perspective.

Conclusion: LIPUS is costlier and no more effective than care as usual, and the ICER per QALY exceeds the range acceptable to payers and decision-makers for adoption (ie, less than $50,000 per QALY).

Δ OTA Grant

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.